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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,300	06/23/2006	Yoshinori Amano	2006_1022A	9011

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EXAMINER	
MA, JAMESON Q	

ART UNIT	PAPER NUMBER
1775	

NOTIFICATION DATE	DELIVERY MODE
12/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/584,300	AMANO ET AL.	
	Examiner	Art Unit	
	JAMESON Q. MA	1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9, 16, and 72-97* is/are pending in the application.

4a) Of the above claim(s) *9 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 72-75, 78-80, 83-91, and 93-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 2001/0055812) in view of Andersson et al. (US 2004/0120856).

The Mian reference has been interpreted two separate ways to reject the following claims. These interpretations have been designated as Interpretation 1 and Interpretation 2. The Mian reference has been interpreted generically with regard to the following limitations regarding a ‘plate’ and 'channel':

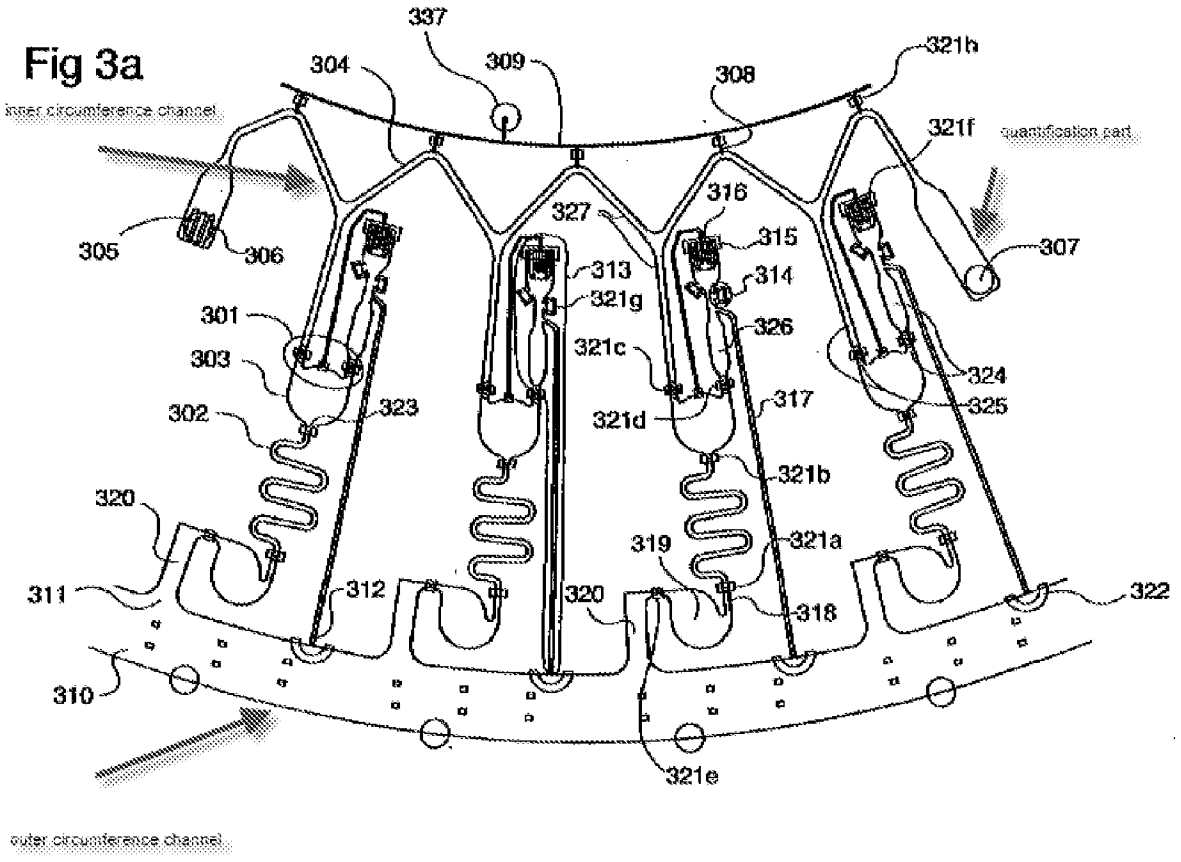
Regarding claim 72, Mian discloses a plate (see figs. 1A-1C and [0051]: Microsystems on a disk) on which a channel pattern is formed, said channel pattern comprising a first channel into which a buffer agent is injected, and a second channel having, in a portion thereof, a quantification part that has a portion common to the first channel.

Mian does not teach a plate on which a channel pattern is formed, said channel pattern comprising a first channel having a round shape comprising an inner circumference channel for injecting a buffer agent and an outer circumference channel serving as a measurement area for performing electrophoresis, and a second channel having, in a portion thereof, a quantification part that has a portion common to the first

channel, and holds a predetermined amount of a biological sample, said biological sample being injected into the second channel.

Mian does teach that centripetal force motivates fluid movement through the substrate (see abstract). Andersson teaches a microfluidic unit that also uses spinning and rotation in ordinary operation (see [0019]).

The following annotated figure of Andersson shows the structural elements that correspond to the instant claims.



The channels are fully capable of holding a predetermined amount of a biological sample, said biological sample being injected into the channel including the quantification part. It is noted that these limitations are viewed as materials worked on by the claimed apparatus. Neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

Mian teaches that microfluidic systems should work in the nanoliter reagent range (see [0041]). Andersson additionally teaches that microfluidic systems should work in the reagent range (see [0018]).

It would have been obvious to one of ordinary skill in the art at the time of invention to substitute for, or in the alternative, additionally provide in the microfuidic system of Mian, the system taught by Andersson because doing so would have resulted in nothing more than the simple substitution of microfluid discs which utilize spinning or centripetal forces to function, as taught by both Mian and Andersson.

Interpretation 1:

For this interpretation, the loader from figs. 13A-13C and [0215], is viewed as a filling unit capable of filling a buffer agent into the first channel of the plate while filling a

biological sample into the second channel including the quantification part, and thereafter, making a predetermined amount of the biological sample remain in the quantification part of the second channel to add the predetermined amount of the biological sample to the buffer agent.

For this interpretation, the micromanipulation device (see [0044], [0170], and figs. 14A-14E) is viewed as a discrimination unit capable of making a predetermined amount of the biological sample that is held in the quantification part migrate in a buffer agent to discriminate the biological sample that migrates in the buffer agent.

Interpretation 2:

For this interpretation, the micromanipulation device (see [0044], [0170], and figs. 14A-14E) is viewed as a filling unit capable of filling a buffer agent into the first channel of the plate while filling a biological sample into the second channel including the quantification part, and thereafter, making a predetermined amount of the biological sample remain in the quantification part of the second channel to add the predetermined amount of the biological sample to the buffer agent.

For this interpretation, the loader from figs. 13A-13C and [0215] is viewed as a discrimination unit capable of making a predetermined amount of the biological sample that is held in the quantification part migrate in a buffer agent to discriminate the biological sample that migrates in the buffer agent.

The following dependent claims are rejected under Interpretation 2.

For claim 73, Andersson discloses the apparatus wherein said plate has a buffer agent injection part connected to the first channel (inlet 305), a sample injection part connected to the second channel (321). Andersson further discloses an air hole (vent 308)) connected to the sample injection part in the second channel, and Mian discloses said filling unit is capable of rotating the plate (see [0043]),

The limitation 'in which the buffer agent is injected into the buffer agent injection part and the sample is injected into the sample injection part, thereby to make the buffer agent stored in the buffer agent injection part flow into the first channel by a centrifugal force, and simultaneously, make the biological sample stored in the sample injection part flow up to a first flow position that does not reach the quantification part in the second channel' is viewed as intended use of the claimed device. A recitation directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art, if the prior art has the capability to so perform.

The manipulation device which rotates the sample is viewed as capable of pressurizing the sample injection part (see [0049]: fluid transport by means of centripetal acceleration would result in a pressurization of the sample inlet port). The limitation 'to make the biological sample in the second channel flow from the first flow position up to a second flow position including the quantification part in the second channel, and thereafter, rotates the plate to separate the biological sample in the second channel so that a predetermined amount of the biological sample remains in the quantification part of the second channel' is viewed as intended use of the claimed device. A recitation directed to the manner in which a claimed apparatus is intended to

be used does not distinguish the claimed apparatus from the prior art, if the prior art has the capability to so perform.

For claim 88, Andersson discloses the device with a plate with injection parts and air hole which is capable of rotation and is capable of rotation and pressurization as disclosed above. Further, the device is capable of performing aspiration from the air hole. (see fig. 3a, vent 308).

For claims 74 and 89, Mian teaches the manipulation device comprises a motor (see [0170]), whose controller is also viewed as a pressure control part (see [0170]).

For claims 78 and 91, Mian discloses both a heater and a thermistor (see [0150]). It is unclear from the claims if there is a limitation regarding the orientation of the heater and the thermistor. If so, Mian still discloses that thermal devices can be applied to the disk as a whole or in specific areas on the disk (see [0150]) which is viewed to meet the instant claim limitation.

For claims 86 and 94, Mian teaches the discrimination unit includes an optical detector (see figs. 14A-14F: photodiode). The optical device is viewed as capable of 'discriminating the biological sample on the basis of the result of detection.'

Modified Mian discloses all of the claim limitations as set forth above.

Interpretation 2 is used to reject the following claims.

For claims 75, 87, and 90, Mian discloses (see figs. 13A-14F) that the manipulation device (filling unit) is at a lower part of the apparatus than the loader (discrimination unit). Additionally, as is evident from the same figures and [0215] there

must be some vertical displacement between the disk and the loader. It is not explicitly disclosed that the optical detector is disposed on an elevation stage (implying that the manipulation device has a height adjustment unit for vertical displacement). However, since vertical displacement is required for the device to operate, and since there are only two components that can accomplish this displacement, it would have been obvious to one of ordinary skill in the art at the time of invention to configure the manipulation device of Mian to perform the displacement, because the exact placement of the vertical displacement mechanism (elevation stage) would have been nothing more than an engineering design choice, which was identified by Mian, obvious to one of ordinary skill in the art at the time of invention barring any unexpected results arising from the exact placement of the vertical displacement mechanism (elevation stage) within device.

This rejection of claim 78 is in the alternative to the one above.

For claims 78-80, Mian discloses both a heater and a thermistor (see [0150]). It is unclear from the claims if there is a limitation regarding the orientation of the heater and the thermistor. If so, Mian still discloses that thermal devices can be applied to the disk as a whole or in specific areas on the disk (see [0150]). If the exact placement claimed is not viewed to be explicitly met by Mian, the exact placement of the heating devices would have been nothing more than an engineering design choice, which was identified by Mian, obvious to one of ordinary skill in the art at the time of invention barring any unexpected results arising from the exact placement of the heating elements within device.

For claims 83 and 93, Mian discloses that electrophoresis is performed and explicitly discloses the placement of the positive electrode (see [0321]). While the reference does not explicitly disclose the negative electrode, for gel electrophoresis to occur, a negative electrode must be present in order for the necessary electric field to be generated. With respect to the exact placement of the electrodes, exact placement of the heating devices would have been nothing more than an engineering design choice, which was identified by Mian, obvious to one of ordinary skill in the art at the time of invention barring any unexpected results arising from the exact placement of the electrodes in the device.

For claim 84, any portion of the plane of the disk is viewed as a 'cleaning portion and the remaining limitations to the electrodes being cleaned are viewed as intended use of the claimed device.

For claim 85, the limitations to the sample and buffer agent are regarded as materials worked on. Neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

3. Claims 73, 81-82, 88 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 2001/0055812) in view of Andersson et al. (US

2004/0120856), as applied to claims 72-75, 78-80, 83-91, and 93-94 above, and further in view of Miyake et al. (US 5,174,162).

Modified Mian discloses all of the claim limitations as set forth above. This rejection of claims 73 and 88 is in the alternative to the one above

Interpretation 1 is used to reject the following claims:

Regarding claims 73 and 88, Mian does not disclose that the loader from figs. 13A-13C and [0215], viewed as the filling unit, is capable of rotating the plate and has a motor. However, Mian does disclose in fig. 13C a multiple loader for the disk which is in a radial arrangement.

Miyake discloses a pipetting system in a radial arrangement wherein six sets of pipetters are equally spaced in a radial arrangement. The pipetters move along a circumferential path picking up reagents, depositing them into an analyzer, and then are moved to a washing station (see C7L42-C8/L31). Miyake discloses that the disc (40) rotates and that the apparatus comprises a rotor and that the means for moving the disc 40 are not shown.

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the pipetting system of Miyake into the loading device of modified Mian in order to allow pipettes to pick up reagents, deposit them, and then be washed in a continuous manner as taught by Miyake.

While modified Mian (Miyake) does not disclose a motor on the filling unit, it is interpreted that a motor must be present in order to effect the rotation of the disc (40) disclosed by Miyake.

Modified Mian discloses all of the structural limitations required by claims 73 and 88 as the filling unit is now capable of rotating a plate.

Alternatively, assuming arguendo that no motor is disclosed, it would have been obvious to one of ordinary skill in the art at the time of invention to use a motor as the means for effecting rotation of disc (40) because would have been to select the most efficient and controllable means for effecting rotation of a disk.

Regarding claims 81-82, and 92 the manipulation device (discrimination unit), has a fitting pin (see Mian figs. 14A-14F: the projection where the disk rests on the manipulation device is a fitting pin), and the plate has a fitting hole (see figs. 14A-14F: the disk is a compact disk with an aperture in its center). The plate (disk) is intended to be fixed to the discrimination unit (mating of the disk and manipulation device), and as disclosed above, the manipulation device has a motor which rotates. Further, the photodiode of the manipulation device (figs. 14A-14F) is viewed as fully capable of acting as a positioning mark detection sensor for detecting a mark provided on the plate.

4. Claims 95-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 2001/0055812) in view of Andersson et al. (US 2004/0120856), as

applied to claims 72-75, 78-80, 83-91, and 93-94 above, and further in view of Tang (US 2002/0183000).

Regarding claims 95-97, modified Mian discloses all of the claim limitations as set forth above. Additionally, Mian is generally directed to analysis wherein microfluidic channels are incorporated to a structure resembling a compact disc and is spun/analyzed by suitable spinning means as discussed above.

The reference does not explicitly disclose a fan.

Tang discloses that fans are used in compact disc drives (see [0002]). Tang further discloses a fan with baffles (26A, 26B, 28A, and 28B, viewed as L-shaped: see [0051]). Additionally, Tang discloses that effective fan filter units are needed to keep particle contents within clean rooms at acceptable levels and to circulate the air (see [0002]). The fan of Tang comprises a filter (see [0034] and [0051]). A 'film' here is interpreted to be a thin sheet of any material and since the filter (32) filters out air particles it is thus a 'porous film.'

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the fan of Tang into the compact disc spinner of Mian in order to allow for filtration of air and cooling of the device.

5. Claims 76-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 2001/0055812) in view of Andersson et al. (US 2004/0120856) as applied to claims 72-75, 78-80, 83-91, and 93-94 above, and further in view of Shimizu (US 2002/0014191).

Regarding claims 76-77, modified Mian discloses all of the claim limitations as set forth above.

The reference does not explicitly disclose that the loader (discrimination unit) is hung via a spring from a ceiling board.

However, as is evident from the same figures and [0215] there must be some vertical displacement between the disk and the loader.

Shimizu discloses a hollow needle which is capable of vertical displacement via a coil compression spring (357, see [0294]).

It would have been obvious to one of ordinary skill in the art at the time of invention to vertically displace the multiple loader of modified Mian with a coil spring as taught by Shimizu because doing so would have allowed for a known exemplary and controllable method for raising and lowering a syringe/needle/pipette device. Additionally, for claim 77, the loaders themselves are viewed as pressure control units.

Response to Arguments

6. Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMESON Q. MA whose telephone number is (571)270-7063. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571)272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JM
December 3, 2010

/Michael A Marcheschi/
Supervisory Patent Examiner, Art Unit 1775